

## 4. INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**Complete if Known**

Application Number	09/986,381
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<b>Filing Date</b>	<b>November 8, 2001</b>
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First Named Inventor	Steven S. Sommer et al.
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Group Art Unit	1637
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Examiner Name Shar S. Hashemi

Teresa Strainle de

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Attorney Docket Number 1954-360

## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

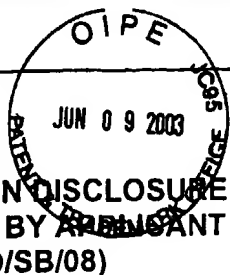
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee of Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office <sup>3</sup> Code	Number <sup>4</sup>	Kind <sup>5</sup> (if known)			
TS	✓	PCT	WO 99/06598	A2	ONCORMED, INC.	02-11-1999	

Examiner Signature	Teresa Strzelczyk	Date Considered	4/7/04
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<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code. <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language translation is attached. AB indicates that only an English language abstract is attached.





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(PTO/SB/08)

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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
TS	A	2002/0098166	A1	HAVEMANN et al. duplicate	07-25-2002
	B	6,071,726	A	DIAMANDIS et al. duplicate	06-06-2000
TS	C	6,342,217	B1	LINK, JR. et al. duplicate	01-29-2002

FOREIGN PATENT DOCUMENTS

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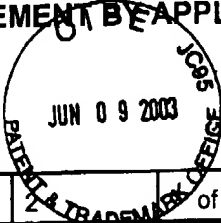
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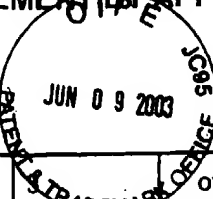
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			Examiner Name	Sher S. Hashemi Teresa Sinelechia
Sheet 2 of 3	Attorney Docket Number		1954-360	
<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published		
TS	D ✓	JANE COLE, et al., "International Commission for Protection Against Environmental Mutagens and Carcinogens"; Mutation Research, 304 (1994) pp33-105, 1994.		
	E ✓	ALAN S. JONASON, et al., "Frequent clones of p53-mutated keratinocytes in normal human skin"; Proc. Natl. Acad. Sci. USA, Vol. 93, pp14025-14029, November 1996.		
	F ✓	S. PERWEZ HUSSAIN, et al., "Increased p53 mutation load in nontumorous human liver of Wilson disease and hemochromatosis: Oxyradical overload diseases"; PNAS, pp12770-12775, Vol. 97, No. 23, November 7, 2000.		
	G ✓	S. PERWEZ HUSSAIN, et al., "Mutability of p53 Hotspot Codons to Benzo(a)pyrene Diol Epoxide (BPDE) and the Frequency of p53 Mutations in Nontumorous Human Lung"; Cancer Research 61, pp6350-6355, September 1, 2001.		
	H ✓	FERNANDO AGUILAR, et al., "Aflatoxin B <sub>1</sub> induces the transversion of G→T in codon 249 of the p53 tumor suppressor gene in human hepatocytes"; Proc. Natl. Acad. Sci. USA, Vol. 90, pp.8586-8590, September 1993.		
	I ✓	LOREL M. COLGIN, et al., "The unexpected landscape of in vivo somatic mutation in a human epithelial cell lineage"; PNAS, February 5, 2002, Vol. 99, No. 3, pp14437-1442.		
	J ✓	LESLIE RECIO, et al., "DNA sequence analysis of in vivo hprt mutation in human T lymphocytes"; Mutagenesis, Vol. 5, No. 5, pp505-510, 1990.		
	K ✓	NEAL OF CARIELLO, et al., "Analysis of Mutations Occurring at the Human hprt Locus" J. Mol. Biol. (1993) 231, pp41-57.		
	L ✓	VERNON E. WALKER, et al., "Frequency and Spectrum of Ethylnitrosourea-induced Mutation at the hprt and lacI Loci in Splenic Lymphocytes of Exposed lacI Transgenic Mice"; CANCER RESEARCH 56, pp4654-4661, October 15, 1996.		
	M ✓	THOMAS R. SKOPEK, et al., "Relative Sensitivity of the Endogenous hprt Gene and lacI Transgene in ENU-Treated Big Blue™ B6C3F1 Mice"; Environmental and Molecular Mutagenesis 26:9-15 (1995).		
TS	N ✓	THOMAS R. SKOPEK, et al., "Mutagenic Response of the Endogenous hprt Gene and lacI Transgene in Benzo[a]pyrene-Treated Big Blue™ B6C3F1 Mice"; Environmental and Molecular Mutagenesis 28:376-384 (1996).		
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Sheet	3 of 3	Attorney Docket Number	1954-360

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
TS	O ✓	OLGA O. MOTORNA, et al., "Analysis of lacI mutations in Big Blue® transgenic mice subjected to parasite-induced inflammation"; Mutation Research, 484 (2001), pp69-76.
	P ✓	SUSAN E. ANDREW, et al., "A novel lacI transgenic mutation-detection system and its application to establish baseline mutation frequencies in the scid mouse"; Mutation Research, 357 (1996), pp57-66.
	Q ✓	TETSUYA ONO, et al., "Age-associated increase of spontaneous mutant frequency and molecular nature of mutation in newborn and old lacZ-transgenic mouse"; Mutation Research, 447 (2000), pp165-177.
	R ✓	GREGORY R. STUART, et al., "Mutation Frequency and Specificity With Age in Liver, Bladder and Brain of lacI Transgenic Mice"; Genetics Society of America, 154:pp1291-1300, (March 2000).
	S ✓	P.D. LEWIS, et al., "Spontaneous mutation spectra in supF: comparative analysis of mammalian cell line base substitution spectra"; Mutagenesis, Vol. 16, No. 6, pp503-515, 2001.
	T ✓	TAKEHIKO NOHMI, et al., "Recent advances in the protocols of transgenic mouse mutation assays"; Mutation Research, 455 (2000), pp191-215.
	U ✓	JOHN A. HEDDLE, et al., "In Vivo Transgenic Mutation Assays"; Environmental and Molecular Mutagenesis, 35:253-259 (2000).
	V ✓	SUSAN E ANDREW, et al., "Base transitions dominate the mutational spectrum of a transgenic reporter gene in MSH2 deficient mice"; Oncogene (1997) 15, pp123-129.
	W ✓	SUSAN E. ANDREW, et al., "Mutagenesis in PMS2- and MSH2-deficient mice indicates differential protection from transversions and frame shifts"; Carcinogenesis, Vol. 21, No. 7, pp1291-1295, 2000.
TS	X ✓	KENTARO HORIKAWA, et al., "Frequent detection of T cells with mutations of the hypoxanthine-guanine phosphoribosyl transferase gene in patients with paroxysmal nocturnal hemoglobinuria"; Blood 1 January 2002, Vol. 99, No. 1, pp24-29.
	Y ✓	CLIVE R. TAYLOR, M.D., Ph.D., et al., "Antigen Retrieval for Immunohistochemistry Status and Need for Greater Standardization"; Applied Immunohistochemistry, 4(3):144-166, 1996. <i>duplicate</i>

Examiner Signature	<i>Terra Hnedelia</i>	Date Considered	7/7/04
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